



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,010	11/09/2005	Lucie Germain	JG-SB-5208	5199
26418	7590	01/02/2008		
REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650			EXAMINER LILLING, HERBERT J	
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			01/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,010

Applicant(s)

GERMAIN ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. This application is a 371 of PCT/CA03/01079 filed July 16, 2002 which claims benefit of U. S. Provisional Application 60/394,004 filed July 16, 2002.
2. Claims 1-25 are present in this application.
3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4 and 7-19, drawn to a method for preparing a human or animal tissue from at least one sheet of living tissue, the method comprising the steps of: (a) arranging said at least one sheet of living tissue to form a multi-layer stack of living tissue; and (b) applying a compressive force in a direction normal to the surface of the multi-layer stack of living tissue with a force-applying means at a pressure and for an amount of time sufficient to compress layers of tissue together for inducing adjacent layers of tissue to fuse or adhere to each other.

Group II, claims 5-6, drawn to a method of claim 1 which further comprising **a step of anchoring said multi-layer stack of living tissue with anchoring means before said step (b)** of applying a force, wherein said anchoring means applies sufficient tension across said multi-layer stack of living tissue to prevent shrinkage and/or maintain cellular differentiation and/or induce fiber orientation.

Group III, claims 20-25, drawn to a method for preparing a planar human or animal tissue suitable for use in making a multi-layer tissue construct from at least one sheet of living tissue, the method comprising the steps of: (a) arranging said at least one sheet of living tissue on a substantially flat support surface; and (b) anchoring said at least one sheet of living tissue to the support surface with an adjustable anchor-means comprised of a multiplicity of spaced apart anchors, wherein the anchors are suitable for (1) applying sufficient tension across the sheet of living tissue to prevent shrinkage and/or maintain cellular differentiation and/or induce

orientation of cells in said at least one sheet of living tissue and (2) allowing contraction of said at least one sheet of living tissue once a predetermined threshold of tension is exceeded across the sheet of living tissue

The inventions or groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1 is evidenced in view of the prior art of record drawn to US 5,955,110; US 5,885,619; US 6,176,880; US 5,922,028 and US 6,287,370.

Inventions I/II and III are drawn to separate and patentably distinct process steps. Invention I or II does not require the specifics of Invention III to prepare a planar tissue on a flat support surface. In addition, Invention I do not require the specifics of Invention II of being anchored .

Because these inventions are independent or distinct for the reasons given above and there would be a **serious burden on the examiner if restriction is not required** because the inventions require a different field of search due to divergent subject matter for a computerized search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. This application contains claim(s) directed to at least one living tissue obtained by culturing cells in vitro:

A- Wherein the cells are selected from the group consisting of:

- a) embryonic stem cells,
- b) post-natal stem cells,
- c) adult stem cells,
- d) mesenchymal cells,

If (d) is selected further election wherein the cells are selected from the group consisting of

- m- fibroblasts,
- n- interstitial cells,
- o- endothelial cells,
- p- smooth muscle cells,
- q- skeletal muscle cells,
- r- myocytes,
- s- chondrocytes,
- t- adipocytes,
- u- fibrocytes,
- v- ectodermal cells,
- w- other please specify.

- e) hepatocytes,
- f) islet cells,
- f) parenchymal cells,
- g) osteoblasts and other cells forming bone or cartilage,
- h) nerve cells,
- i) other cells-please specify,
- j) combination of any of the above – please specify.

B. Wherein the living tissues selected above is :

1. one sheet,
2. two sheets,
3. more than two sheets-please specify.

C. Wherein the living tissue sheet is selected from the group consisting of

- t- a skin tissue,

- u- a corneal tissue,
- v- a cardiac valve tissue,
- w- a connective tissue,
- x- a mesenchymal tissue,
- y- other please specify.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3 and 20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. **If claims are added after the election, applicant must indicate which are readable upon the elected species.**

MPEP § 809.02(a).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with

this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species from above paragraph 4 for each of A, [one species from A a or Ab orand if Ad is elected there is a further election]; B [one species from B1 , B2 or B3] and one species from C [C1 or C2 or C3] and an invention from I or II or III, to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

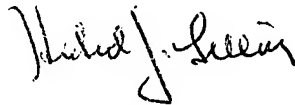
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Application/Control Number:
10/522,010
Art Unit: 1657

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1657**
December 18, 2007



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657